



12-08-06

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1614

PTO/SB/21 (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number 09/903,665-Conf. #3102

Filing Date July 13, 2001

First Named Inventor Giancarlo Santus

Art Unit 1614

Examiner Name Frederick F. Krass

Attorney Docket Number 04266/1006895-US2

**ENCLOSURES (Check all that apply)**☒ Fee Transmittal Form☒ Fee Attached☐ Amendment/Reply☐ After Final☐ Affidavits/declaration(s)☐ Extension of Time Request☐ Express Abandonment Request☒ Information Disclosure Statement☐ Certified Copy of Priority Document(s)☐ Reply to Missing Parts/  
Incomplete Application☐ Reply to Missing Parts under  
37 CFR 1.52 or 1.53☐ Drawing(s)☐ Licensing-related Papers☐ Petition☐ Petition to Convert to a  
Provisional Application☐ Power of Attorney, Revocation  
Change of Correspondence Address☐ Terminal Disclaimer☐ Request for Refund☐ CD, Number of CD(s) \_\_\_\_\_☐ Landscape Table on CD☐ After Allowance Communication  
to TC☐ Appeal Communication to Board of  
Appeals and Interferences☐ Appeal Communication to TC  
(Appeal Notice, Brief, Reply Brief)☐ Proprietary Information☐ Status Letter☒ Other Enclosure(s) (please  
Identify below):3 References attached  
Return Receipt Postcard

Remarks

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name DARBY &amp; DARBY P.C.

Signature

Printed name Irina E. Vainberg

Date December 6, 2006

Reg. No. 48,008



Application No. (if known): 09/903,665

Attorney Docket No.: 04266/1006895-US2

## Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. in an envelope addressed to:

MS ~~Missing Parts~~ *Amendment*  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on December 6, 2006  
Date

*Lillian Garcia*  
\_\_\_\_\_  
Signature

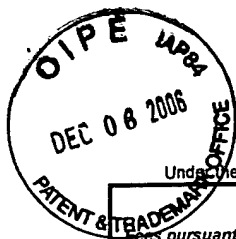
*Lillian Garcia*  
\_\_\_\_\_  
Typed or printed name of person signing Certificate

N/A  
Registration Number, if applicable

(212) 527-7700  
Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Supplemental Information Disclosure Statement (5 pages)  
IDS (Citation) by Applicant (9 References, 3 attached) (1 page)  
Transmittal (1 page)  
Fee Transmittal (1 page)  
Check in the amount of \$180.00 12807



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PTO/SB/17 (07-06)  
Approved for use through 01/31/2007. OMB 0651-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

<b>Effective on 12/08/2004.</b> Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).		<b>Complete if Known</b>		
<b>FEE TRANSMITTAL</b> <b>For FY 2006</b>		Application Number	09/903,665-Conf. #3102	
		Filing Date	July 13, 2001	
		First Named Inventor	Giancarlo Santus	
		Examiner Name	Frederick F. Krass	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Art Unit	1614	
TOTAL AMOUNT OF PAYMENT	(\$)	180.00	Attorney Docket No.	04266/1006895-US2

**METHOD OF PAYMENT (check all that apply)**

☒ Check    ☐ Credit Card    ☐ Money Order    ☐ None    ☐ Other (please identify): \_\_\_\_\_

☐ Deposit Account    Deposit Account Number: 04-0100    Deposit Account Name: Darby & Darby P.C.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below    ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17    ☒ Credit any overpayments

**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims    Extra Claims    Fee (\$)    Fee Paid (\$)    Multiple Dependent Claims

\_\_\_\_\_ - = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_    Fee (\$)    Fee Paid (\$)

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims    Extra Claims    Fee (\$)    Fee Paid (\$)

\_\_\_\_\_ - = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

HP = highest number of independent claims paid for, if greater than 3.

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets    Extra Sheets    Number of each additional 50 or fraction thereof    Fee (\$)    Fee Paid (\$)

\_\_\_\_\_ - 100 = \_\_\_\_\_ /50 \_\_\_\_\_ (round up to a whole number) x \_\_\_\_\_ = \_\_\_\_\_

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement    180.00

<b>SUBMITTED BY</b>			
Signature		Registration No. (Attorney/Agent)	48,008
Name (Print/Type)	Irina E. Vainberg	Telephone	(212) 527-7634
		Date	December 6, 2006



Docket No.: 04266/1006895-US2  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Giancarlo Santus et al.

Application No.: 09/903,665

Confirmation No.: 3102

Filed: July 13, 2001

Art Unit: 1614

For: THERAPEUTIC COMPOSITIONS FOR  
INTRANASAL ADMINISTRATION WHICH  
INCLUDE KETOROLAC

Examiner: Frederick F. Krass

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Supplemental Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:  
(Check one of the boxes A-D)

- ☐ A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above identified national application
- ☐ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☒ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was (check one of boxes (a) or (b))
- ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- ☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☒ ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(i) a check in the amount of \$180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was

(check one of the boxes "a" and "b" below:)

- ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- ☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☒ A. Pursuant to the 37 C.F.R. § 1.98(a)(2)(ii), a copy/copies of the U.S. **Patent(s) and/or U.S. Patent Application Publication(s)** on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) \_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☒ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

Serial No. 07/875,700      filed    4/29/1992  
Serial No. 08/383,707      filed    2/1/1995

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

- ☐ 3. Cite No(s). \_\_\_\_\_ are not in the English language.  
In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.
- ☐ The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.
- ☐ A concise explanation of document(s) \_\_\_\_\_ can be found on the attached sheet.

- ☒ 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).
- ☐ 5. Other information being provided for the examiner's consideration follows:

[A/An \_\_\_\_\_ Search Report, dated \_\_\_\_\_, which issued during the prosecution of \_\_\_\_\_ Application No. \_\_\_\_\_ which corresponds to the present application.]

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Early and favorable consideration is earnestly solicited.

Our check in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p) is enclosed. The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: December 6, 2006

Respectfully submitted,

By 

Irina E. Vainberg

Registration No.: 48,008

DARBY & DARBY P.C.

P.O. Box 5257

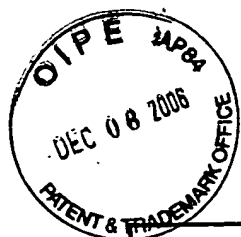
New York, New York 10150-5257

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant





PTO/SB/08A/B (09-06)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/903,665-Conf. #3102
				Filing Date	July 13, 2001
				First Named Inventor	Giancarlo Santus
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	04266/1006895-US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA*	US-4,919,939	04-24-1990	Baker	
	AB*	US-4,994,439	02-19-1991	Longenecker et al.	
	AC*	US-5,049,386	09-17-1991	Eppstein et al.	
	AD*	US-5,091,182	02-25-1992	Ong et al.	
	AE*	US-5,143,731	09-01-1992	Viegas et al.	
	AF*	US-5,855,907	01-05-1999	Peyman	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
	BA	WO-90/001322	02-20-1990	Hussain, et al.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	Rubin, M.D. et al Comparison Long-Term Safety of Ketorolac Tromethamine and Aspirin in the Treatment of Chronic Pain.Pharmacotherapy (1990) 10(6pt. 2) pg. 106S-110S	
	CB*	Santus, et al., Nasal Formulations of Ketorolac Tromethamine Technological Evaluation-Bioavailability and Tolerability in Rabbits, IL Farmaco, 48 (12), 1709-1723; 1993	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	Date Considered
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